THE UNIVERSITY OF TEXAS AT ARLINGTON

ENVIRONMENTAL HEALTH AND SAFETY

February 5, 2003

Minh Thomas
Select Agent Program
Centers for Disease Control and Prevention
Mail Stop E-79
1600 Clifton Road NE
Atlanta, GA 30333

Re: Comments on Select Agent Program Final Interim Rules 42 CFR 73

Dear Ms. Thomas:

The University of Texas System Environmental Advisory Committee ("UTS EAC")[1] appreciates the opportunity to provide comments on the CDC's Final Interim Rules regarding the possession, use and transfer of select agents. The University of Texas System supports the strengthening of regulatory safeguards surrounding biological agents and toxins and is committed fully to protecting human health and the environment at all of our components that conduct education and research in this increasingly important area. Significant select agent research and educational activities currently occur at 11 of the 15 UTS components and we anticipate that our research programs will continue to expand to meet an increased threat of bioterrorism. We hope to assist this process by offering the following comments and by raising some questions that may be addressed in subsequent rulemakings to provide further clarification for the benefit of personnel at UTS components who must interpret and implement these rules.

First, we support the comments that were submitted by Howard Hughes Medical Institute on January 21, 2003 (03-SAR-013 on the CDC website) and the joint comments of the Association of American Universities, the American Council on Education and the Council on Governmental Relations submitted on February 3, 2003 (03-SAR-033). Both sets of comments raise issues critical to successful implementation of the new biosecurity requirements at research and educational facilities. Adoption of the recommendations by the CDC will lessen administrative burdens and encourage effective performance-based and risk-based security plans while ensuring

[1] The Environmental Advisory Committee is composed of the Environmental Health and Safety Directors from each University of Texas System component institution, including 9 academic campuses located in Austin, El Paso, Dallas, Arlington, San Antonio, the Permian Basin (Odessa), Tyler, and the Rio Grande Valley (Brownsville and Edinburg) and 6 health institutions (Medical Branch in Galveston, M.D. Anderson Cancer Center in Houston, Southwestern Medical Center at Dallas, Health Science Centers at Houston and San Antonio, and the Health Center at Tyler).

The University of Texas System educates more than 169,000 students, has over 86,000 faculty and staff and, out of a $7 billion annual operating budget, spends approximately $1.2 billion on research activities. The federal government contributes approximately $700 million toward this research effort.

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appropriate availability of biological agents and toxins for research, education and other legitimate purposes. We urge your careful consideration of those comments and incorporation of the suggested improvements into the Final Rule.

Second, we would like to highlight and emphasize several of the rule sections creating the greatest uncertainty and potential implementation issues for our components:

§73.1 Definitions

A definition of "access" should be added.

The issue of access is a critical element of these rules and will drive implementation strategies ranging from security planning to the number of individuals that must undergo the Department of Justice security risk assessments. This is an especially challenging issue for research undertaken in an "open lab" environment. Under the current rules, facilities are left to guess how expansively or restrictively to construe this term, risking that CDC and DOJ may be flooded with requests for security risk assessments for individuals who have no ability to possess or control select agents, thereby jeopardizing the ability of individuals who need expeditious approval to receive it. The rules should adopt a reasonable and objective definition to give adequate guidance and we believe "The ability to gain physical control of select agents and toxins" is a definition that should be adopted.

§73.7(c)

HHS and USDA should consolidate regulatory oversight as Congress directed.

At least one of our components may have to send in duplicate application packages to HHS and USDA because of research with select agents under the exclusive jurisdiction of those agencies. Such duplication is inefficient, should be unnecessary and is contrary to the statutory requirement that "the Secretary of Health and Human Services and the Secretary of Agriculture shall, to the greatest extent practicable, coordinate activities to achieve the following: (2) To minimize the administrative burden on persons subject to regulation under both of such programs...." H.R. 3448, §221.

HHS and USDA should also review each agency's rules and better conform them so that inconsistent standards are not set or confusing ambiguities created. For example, the USDA rules provide a definition of "Responsible Official", the CDC rules do not. We would recommend that the CDC rules adopt the same definition. Although largely parallel and consistent, there are other unnecessary deviations in the structure and language of the two agencies' rules that run counter to the mandates of Subtitle C of H.R. 3448.

§73.7(f)

Entities should have the option to apply for a single certificate of registration for all campus buildings under the effective control of the Responsible Official ("RO").

The current definition based on a "single mailing address" will create administrative inefficiencies and result in unnecessary application packages being submitted, given the diverse geographic configuration of many of our components. Entities should be allowed to make a performance-based decision on the most efficient span of control of the appointed RO, regardless of the existence of more than one physical location with a separate mailing address.

§73.7(g)

The certificate of registration should be valid for five years.

We support the recommendation that the certificate of registration be valid for up to five years. Most of our components will have to amend and update registration information as required under the rules during the validity period so we see no reason to have a validity period shorter than that for security risk assessments.

§73.8

More certainty must be provided concerning security risk assessment procedures.

We support the comments that more detail must be provided concerning these procedures, including appeal procedures. We assume that HHS is in serious discussion with DOJ on how these assessments are going to be conducted in an expeditious and timely manner so that ongoing research and education efforts are not disrupted or halted due to bureaucratic inefficiencies. We would propose that entities be allowed to submit the assessment information for the RO, Alternate ROs and those individuals currently conducting research as soon as the DOJ is prepared to receive them (which may be earlier than March 12) so that approvals can be obtained as soon as possible.

§73.9

The RO must have the ability to delegate certain tasks and duties.

We support the approach embodied in this section that an entity can designate the most appropriate individual within the organization to carry out the duties of the RO. We assume that the CDC understands that the RO cannot personally discharge every duty and task for which the RO will be held accountable and that delegation was contemplated under the current rules. We support the comment that this section should make that ability to delegate clear, which will be essential given the size and complexity of many of our components' research and education activities.

§73.11

The security plans must be risk-based and performance-based.

We support the performance-based approach which the rules largely adopt and urge that the CDC give entities flexibility to tailor their security plans to fit their specific circumstances. The security requirements for a large medical institution dealing with multiple select agents in BSL 3 and 4 environments would be inappropriate at an academic institution dealing with one or two low risk select agents. We have components at both ends of the spectrum.

In conclusion, the UTS EAC supports the comments previously submitted by HHMI, AAU, ACE and COGR, with special emphasis on the issues discussed above. We appreciate the ability to provide suggestions on ways to improve our ability to enhance security surrounding the use of select agents while still being able to carry out our missions of research and education.

If you have any questions or need additional information, please contact me at 817-272-2185.

Sincerely,

Craig Powell, Chair
The University of Texas System Environmental Advisory Committee